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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,640	02/07/2001	Babak Nemati		4426

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EXAMINER

HAYES, MICHAEL J

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/777,640	Applicant(s) NEMAT, BABAK	
	Examiner Michael J. Hayes	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 71-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 3763

## **DETAILED ACTION**

### ***Withdrawal of Finality***

The finality of the paper mailed 6/09/04 is withdrawn in view of newly discovered prior art and/or reconsideration of prior art of record in a new light, as discussed below.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, confocal microscope as part of the apparatus and spectral information device as part of the apparatus as recited in claim 73, laser irradiation portion as recited in claim 74, driver portion that drives via iontophoresis, electroporation, acoustic pressure, or application of enhancer, agent, or solvent, as recited in claim 79 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 79-85 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

Art Unit: 3763

the invention. Claims 79-85 are drawn to a method, but are dependent from an apparatus claim. The combination of these two types of claims makes the claims indefinite because it is not known whether Applicant desires to claim a method or an apparatus. Furthermore, though written as method claims, claims 79-85 do not recite any steps. Applicant is advised that if the claims are rewritten as method claims it appears that a double patenting rejection with Application 09/777639 (Notice of Allowance mailed 9/24/04) would be proper.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 71-77, 78, 79, 81, and 84 are rejected under 35 U.S.C. 102(b) as being anticipated by COLEMAN et al.. Coleman discloses an apparatus having a pore forming portion consisting of a needle point, a delivery portion that enables ejection of material from the apparatus into a patient (2:63-67), and a non-invasive optical portion coaxial with the pore forming portion. The optical portion is non-invasive because it is recessed from the end of the needle, enabling the optical portion to remain proximal of tissue when the needle end forms a pore. The apparatus is configured to be capable of delivering a clarifying agent to permeability barriers such as sclera or stratum corneum and applying a chemical enhancer or carrier agent.

Claims 71, 72, 75, 76, 78, 79, 81, 83, 84, 86, 87, 88, 89, and 90 are rejected under 35 U.S.C. 102(b) as being anticipated by MARTINEZ (U. S. Patent No. 4,222,375). Martinez

Art Unit: 3763

discloses an apparatus capable of enhancing the optical transparency of biological tissue comprising a pore forming portion (needle 58), delivery portion (syringe 3:25-26), noninvasive optical portion (optical portion 12, coupled to the pore forming portion and delivery portion, remains outside the patient during use). The apparatus is configured such that the opening is formed, agent delivered, and light emitted when the apparatus is proximal to the sclera because the apparatus is capable of applying a chemical force to form pores for the delivery of the clarifying agent. The pore forming portion is the needle 58 that allows agents to be applied to a barrier from a proximal position. In applying penetrating solvents or carrier agents, clarifying agent, and light the apparatus is capable of being proximal to the permeability barrier. See figs. 3, 4.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 71-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHAN et al. (US Patent No. 6,275,726) in view of COLEMAN. Chan discloses a pore forming portion as a laser, hypodermic needle, or jet injector (3:64-4:3), delivery portion as a syringe, optical portion for diagnostic and therapeutic applications and to provide spectral information. When using the jet injector embodiment disclosed by Chan the device is non-invasive and is capable of remaining proximal to the barrier (1:50-65; 2:24-32; 3:51-67; 4:1-12; 7:25-65; 8:37-40). Chan

Art Unit: 3763

does not disclose combining the pore forming portion and light delivery device as coaxially arranged. Coleman teaches incorporating a pore forming portion and light delivery device in one apparatus in a coaxial arrangement to provide for an apparatus that is easy to use and provides fast results (1:29-46). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Coleman in the apparatus of Chan in order to accomplish the precise application of light during surgical operations in an apparatus that easy to use for quick site-specific applications.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. EDWARDS (US Patent No. 5,833,647) discusses apparatus for delivering agents across permeability barriers. EPPSTEIN (U. S. Patent No. 6,527,716) shows various devices for bypassing a surface permeability layer to deliver agents to covered biological tissues.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (703) 308-2698. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 3763

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh  
13 December 2004



**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**